IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION AND NOVARTIS AG,	)	
Plaintiffs,	)	C.A. No. 15-00474-RGA
v.	)	
WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED,	)	**REDACTED PUBLIC VERSION**
Defendant.	)	

HIKMA'S OPENING BRIEF IN SUPPORT OF ITS
MOTION TO ENFORCE A SETTLEMENT AGREEMENT

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I. INTRODUCTION

Defendant West-Ward Pharmaceuticals International Limited (now known as Hikma Pharmaceuticals International Limited, referred to herein as "Hikma") respectfully requests that the Court enforce [redacted] between Hikma and Plaintiffs Novartis Pharmaceutical Corporation and Novartis AG (together, "Novartis") terminating patent litigation relating to Hikma's ANDA seeking approval for generic everolimus tablets in 2.5 mg, 5 mg, 7.5, mg and 10 mg dosage strengths. (Ex. 1 ("Settlement Agreement").)

Novartis and Hikma struck a deal that permitted Hikma to enter the market at [redacted]. There is no dispute that the first filer has forfeited exclusivity. Yet Novartis seeks to preserve the deal [redacted] by preventing Hikma from obtaining FDA approval.

The parties dispute centers around whether the agreed upon [redacted] contained in the Settlement Agreement really means Hikma could enter the market [redacted] Admittedly, while it is the FDA, not the USPTO, that grants a 6-month extension to patent terms for pediatric exclusivity, that extension necessarily goes hand-in-hand with the patent rights. [redacted] Yet Novartis still maintains that it gave — and Hikma agreed to accept — [redacted].

Hikma therefore requests that the Court require Novartis to comply with the Settlement Agreement by notifying FDA that [redacted]

[redacted] for purposes of obtaining regulatory approval, or a Court order to that effect.

II. FACTUAL BACKGROUND

A. The Everolimus Litigation

Novartis and Hikma engaged in patent litigation before this Court related to various everolimus products for more than six years. Novartis first sued Hikma's predecessor-in-interest, Roxane, in September 2014, asserting infringement against Roxane's ANDA referencing Novartis's ZORTRESS® product. *Generally* Case No. 14-1196 (D. Del.).

Novartis had also received FDA approval for a second everolimus product, marketed as AFINITOR®, at four strengths: 2.5 mg, 5 mg, 7.5 mg, and 10 mg. In late 2014, Novartis sued at least two companies for filing ANDAs referencing the AFINITOR® product.

The first filed ANDA filed referencing the AFINITOR® product was filed by Par.[1] Novartis sued Par on December 18, 2014 in this judicial district. Complaint, *Novartis Pharm. Corp. v. Par Pharm., Inc.*, No. 1:14-cv-1494-RGA, D.I. 1 (D. Del. Dec. 18, 2014). The patents included in the Paragraph IV Certification were U.S. Patent Nos. 5,665,772 ("the '772 patent") and 7,297,703 ("the '703 patent"). *See id.* at ¶¶ 21–23. These three patents gave Par the right to claim "first filer" exclusivity, pursuant to 21 U.S.C. § 355(j)(5)(B)(iv).

Roxane Laboratories, Inc. (now Hikma) filed its ANDA referencing AFINITOR® shortly after Par's ANDA was filed. Novartis sued Roxane on December 23, 2014 in this judicial district. Complaint, *Novartis Pharm. Corp. v. Roxane Labs., Inc.*, No. 1:14-cv-1508-RGA, D.I. 1 (D. Del. Dec. 23, 2014). After the suit was filed, the ANDA was transferred to a Hikma

[1] Par's original ANDA included only the 2.5 mg, 5 mg, and 7.5 mg products. Therefore, they are only the first filer on those strengths. Hikma's ANDA was the first to request approval for the 10 mg product, [redacted]

subsidiary known as West-Ward Pharmaceuticals International Limited. *See* Unopposed Motion to Substitute, No. 1:14-cv-1508, D.I. 117 (D. Del. Feb. 27, 2017).

After the initial complaint for patent infringement was filed, Novartis filed additional complaints for patent infringement related to Hikma's ANDA referencing AFINITOR®, all before this Court. Specifically, Novartis filed Case No. 15-128 on February 5, 2015, and Case No. 15-474 on June 10, 2015.

The proceedings on some patents were stayed pending the outcome of the trial in the ZORTRESS® product litigation. In February 2016, however, the parties reached an agreement [redacted]. (Ex. 2 [redacted].) *See also* Stipulation of Dismissal, *Novartis Pharms. Corp. v. West-Ward Pharms. Int'l Ltd.*, No. 14-1508-RGA, D.I. 110 (D. Del. Mar. 4, 2016). [redacted]. (Ex. 2 at 1.) At that point, those two patents were finally resolved and no longer blocked Hikma's path to FDA approval.

The parties proceeded with discovery regarding the remaining patents, U.S. Patent Nos. 8,410,131 and 9,006,224. This Court held a trial in September 2017 regarding the validity of those patents. In December 2017, the Court issued an opinion that Hikma failed to prove invalidity of the asserted claims. *Novartis Pharm. Corp. v. West-Ward Pharm. Int'l Ltd.*, 287 F. Supp. 3d 505 (D. Del. 2017). Hikma appealed.

Shortly after the Court's opinion issued, the PTAB instituted review of claims of the '131 patent from a petition filed originally by Breckenridge Pharmaceutical, Inc. Decision Institution of Inter Partes Review, No. IPR2017-1592, D.I. 12 (PTAB Jan. 3, 2018). Hikma filed a petition and joined that proceeding. Decision Instituting Inter Partes Review and Granting Motion for

Joinder with IPR2017-1592, No. IPR2018-507, D.I. 10 (PTAB Feb. 20, 2018). The parties engaged in discovery related to the issue of whether the USPTO improperly granted the '131 patent to Novartis in view of the prior art.

Simultaneously, the Federal Circuit heard the appeal of this Court's decision regarding the '131 and '224 patents. Case No. 18-1434 (Fed. Cir.) The Federal Circuit affirmed this Court's ruling on May 13, 2019. *Novartis Pharm. Corp. v. West-Ward Pharm. Int'l Ltd.*, 923 F.3d 1051 (Fed. Cir. 2019).

During the pendency of these litigations, in [redacted] Novartis and Hikma reached a settlement agreement regarding [redacted]. (Ex. 3, [redacted].) [redacted].

B. The Settlement Agreement

Novartis and Hikma ultimately reached a [redacted] ending the litigation. The structure of the Settlement Agreement is straightforward. [redacted] This dispute relates only to the provision [redacted] ("Hikma's ANDA Products").

Novartis and Hikma negotiated other terms providing that, under certain circumstances, [redacted]

[redacted]

as described in 21 U.S.C. § 355(j)(5)(D). The relevant language of [redacted] of the agreement as to this second scenario is emphasized here:

[redacted]

(Ex. 1, § 1.6(ii) at 3 (emphasis added)).

[redacted]

That relevant language is provided below:

[redacted]

[redacted]

(Ex. 1, §§ 3.1-3.2, at 6-7 (emphasis added)). Under the unambiguous terms of the Settlement Agreement, [redacted] Even so, Novartis still denies [redacted].

C. Par Forfeited Its 180-Day Exclusivity, [redacted]

Par was eligible for 180-day exclusivity, but subsequently forfeited that exclusivity because the relevant patents expired before obtaining FDA approval. Par's ANDA No. 207934 was the first ANDA filed for the 2.5 mg, 5 mg, and 7.5 mg strengths of AFINITOR®. Par's first-filer exclusivity was based on the certifications for the '772 and'703 patents. As such, to maintain exclusivity, Par was required to receive FDA approval for its ANDA before the expiration of these patents, not including any pediatric exclusivity. 21 U.S.C. § 355(j)(5)(D)(i)(VI). According to the FDA website, the '772 patent expired September 9, 2019, and both the '703 and '338 patents expired December 6, 2019, not including any pediatric exclusivities. (Ex. 4, Orange Book.)

Par did not receive Final FDA approval for its 2.5 mg, 5 mg, and 7.5 mg strengths of its ANDA No. 207934 until December 9, 2019—three days after expiration of the '703 and '338

patents.[2] (Ex. 5.) Par therefore forfeited its 180-day exclusivity to market its ANDA No. 207934. 21 U.S.C. § 355(j)(5)(D)(i)(VI).

After receiving FDA approval, Par launched its generic 2.5 mg, 5 mg, and 7.5 mg everolimus products in the U.S. market. Par has been permitted by Novartis to sell its products in the U.S. market because of a license, agreement, release, or covenant not to sue for the '772 and '703 patents as part of a separate settlement agreement.[3]

[redacted].

[redacted], the status of each Orange Book-listed patent as to Hikma is summarized below:

Patent	Expiration Date	Pediatric Exclusivity Date	Impact
5,665,772	9/9/2019	3/9/2020	[redacted]
7,297,703	12/6/2019	6/6/2020	[redacted]
7,741,338	12/6/2019	None	[redacted]
8,410,131	11/1/2025	5/1/2026	[redacted]
8,436,010	2/22/2022	8/22/2022	[redacted]
8,778,962	2/18/2022	8/18/2022	[redacted]
9,006,224	7/1/2028	None	[redacted]

D. Novartis Refuses to Allow Hikma to Enter the Market

Hikma received tentative approval for its everolimus products on July 16, 2019. (Ex. 7.) But it cannot receive final approval for its product until the Orange Book-listed exclusivities

[2] The FDA website also indicates that Par Pharmaceuticals received Tentative Approval for its 10 mg strength included in ANDA No. 207934 on the same date. (Ex. 5.)
[3] The '338 patent expired on December 6, 2019 and is not subject to any regulatory exclusivities. As such, it is of no import to the remainder of this litigation.

expire [redacted]. For Orange Book-listed patents, the FDA requires the patent holder to confirm in writing that it has reached an agreement to approve an ANDA as of a specific date. 21 C.F.R. § 314.94(a)(12)(v).

Because the parties settled disputes as to the patents listed in the Orange Book for Novartis's AFINITOR® product, the FDA expects [redacted]. The Settlement Agreement [redacted]

[redacted] As such, Novartis did not fulfill its obligation to [redacted].

The parties have met and conferred on multiple occasions, but have been unable to reach a compromise.

III. THIS COURT HAS AUTHORITY TO ENFORCE THE SETTLEMENT AGREEMENT

The District Court retains jurisdiction over the enforcement of settlements entered into in cases it oversaw. *E.g.*, *Hobbs & Co. v. Am. Investors Mgt., Inc.*, 576 F.2d 29, 33 (3d Cir. 1978); *Leonard v. U of Del.*, 204 F. Supp. 2d 784, 785 (D. Del. 2002). After dismissal of a case, when a dispute over the enforcement of a settlement agreement arises, the district court retains jurisdiction if there is an independent basis for subject matter jurisdiction. *In re Phar-Mor, Inc. Securities Litig.*, 172 F.3d 270, 274 (Fed. Cir. 1999) (citing *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 381-82 (1994)).

Here, this Court retains subject matter jurisdiction because the underlying dispute that the parties resolved was a patent litigation matter, the subject of federal jurisdiction. In addition, subject matter jurisdiction is present at least under 28 U.S.C. § 1332. Plaintiff Novartis Pharmaceutical Corporation is a Delaware corporation and Novartis AG is a Swiss corporation. (D.I. 1, Compl. ¶¶ 2–3; Ex. 1 at 1.) The sole defendant, Hikma, is a foreign corporation, organized under the laws of the United Kingdom. (Ex. 1 at 1.) As such, there is diversity among the parties. 28 U.S.C. § 1332(a)(2). [redacted] Hikma [redacted]. This Court has original jurisdiction over this motion to enforce the settlement. [redacted]. (Ex. 1, § 6.5.)

IV. THE COURT SHOULD REQUIRE NOVARTIS TO TAKE ITS PROMISED STEPS TO ALLOW HIKMA TO ENTER THE MARKET

According to the Settlement Agreement, [redacted]. As such, Hikma should be able to do exactly that: enter the market with its generic products. The

plain language of the Settlement Agreement requires [redacted].A motion to enforce a settlement agreement resembles a motion for summary judgment and employs a similar standard of review. *Parker–Hannifin Corp. v. Schlegel Elec. Materials, Inc.*, 589 F. Supp. 2d 457, 461 (D. Del. 2008). Therefore, a court may grant enforcement if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that ... the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." *Penn. Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for enforcement; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

A. Novartis Must Provide [redacted] According to the Terms of the Settlement Agreement

At this point, Hikma is blocked from obtaining final FDA approval because [redacted]. According to the Orange Book, [redacted], effectively gutting [redacted].

Typically, before [redacted], the patent owner would notify FDA that this period should be waived, to allow approval in time for launch. [redacted] Novartis refuses [redacted], which is why Hikma has been forced to ask the Court for relief.

1. The [redacted] Have Been Met

According to the Settlement Agreement, [redacted]. Par was the first filer on the 2.5, 5, and 7.5 mg strengths, but forfeited its first-filer exclusivity—[redacted] In particular, Par failed to obtain FDA approval before the '772 and '703 patents expired, and so forfeited its 180-day exclusivity. 21 U.S.C. § 355(j)(5)(D)(i)(VI) (requiring approval before "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired").

The FDA has implicitly confirmed forfeiture. On the same day that Par received its FDA approval, the FDA also approved Teva's ANDA No. 210050 for everolimus. (Ex. 6, FDA ANDA No. 210050.) Teva, who was not a first filer, could have only received final approval because the FDA determined that Par had forfeited exclusivity and therefore could not preclude approval of ANDAs held by second filers.

Par launched its generic everolimus products in the United States market on December 10, 2019, as confirmed by a press release from Par's parent corporation. (Ex. 9, Par Press Release at 1.) [redacted] (Ex. 1, § 1.15.) This launch was allowed by an agreement between Par and Novartis.

Taken together, the [redacted]. As such, [redacted]

2. The Settlement Agreement Grants Hikma [redacted]

The bargain struck by Novartis and Hikma [redacted]. The heart of the rights that Novartis granted to Hikma is found is [redacted]. As of [redacted] these sections require Novartis to [redacted]. Novartis is also required to [redacted].

[redacted] (Ex. 1, [redacted] (*Id.* [redacted].) [redacted]

Taken together, Novartis is required to [redacted] The [redacted] are [redacted]

[redacted] After all, Novartis asserted each of these patents against Hikma's predecessors and claimed ownership and control of the patents. Complaint, *Novartis Pharms. Corp. v. Roxane Labs., Inc.*, No. 14-cv-1508-RGA, D.I. 1, ¶¶ 12-15 (D. Del. Dec. 23, 2014). [redacted]

[redacted] (Ex. 1 at 2.)

[redacted]

(Ex. 1, § 3.6.2 at 10-11.)

3. The [redacted] Confirms Hikma Should Be Allowed to Launch No Later Than [redacted]

In fact, [redacted]

[redacted]. (Ex. 2.) That is precisely what Novartis is doing by refusing to [redacted].

A [redacted] is [redacted] *E.g., Transcore, LP v. Elec. Transaction Consultants Corp.*, 563 F.3d 1271, 1275 (Fed. Cir. 2009) ("a non-exclusive patent license is equivalent to a covenant not to sue."); *Spindelfabrik Suessen-Schurr Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft*, 829 F.2d 1075, 1081 (Fed. Cir. 1987) ("[A] patent license agreement is in essence nothing more than a promise by the licensor not to sue the licensee."); *Securus Techs. Inc. v. Global Tel*Link Corp.*, 676 F. App'x 996, 997 (Fed. Cir. 2017); *Verizon Calif. Inc. v. Ronald A. Katz Tech. Licensing, L.P.*, No. 01-cv-9871, 2003 WL 25761597, at *12 (C.D. Cal. Dec. 2, 2003). And a patent license in the Hatch Waxman context would also include any pediatric exclusivity. *Astrazenea AB v. Apotex Corp.*, 782 F.3d 1324, 141-42, 1344 (Fed. Cir. 2015) (discussing and agreeing with district court conclusion that hypothetical license would have necessarily included license to pediatric exclusivity period).

[redacted]. Yet [redacted] At worst, the [redacted] should be found to be ineffective and Hikma should be allowed to launch its product on [redacted].

[redacted]

B. Novartis's Objections Are Incorrect

Novartis has taken the extraordinary position that [redacted] Novartis claims it [redacted]. Nothing could further frustrate the purpose of the Settlement Agreement, and Novartis's position makes no sense. Allowing Novartis to back out of its agreement sets a bad precedent and harms the efforts of other defendants to reliably settle cases in the future.

1. The [redacted] Does Not Negate the Rights Novartis Granted to Hikma

Novartis does not appear to deny that [redacted]. Instead, Novartis argues that [redacted] But this is a misreading of the agreements. [redacted]. *See Astrazeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1341-42

(Fed. Cir. 2015) ([redacted]). Otherwise, [redacted]

2. The [redacted]

Because Novartis [redacted]. A [redacted] does not stand on its own—it only attaches to an already existing patent or regulatory exclusivity. *See* 21 U.S.C. § 355a(b)-(c). According to statute, the [redacted] only attaches if "the court determines that the patent is valid and would be infringed." 21 U.S.C. § 355a(c)(1)(B)(ii). [redacted]. Novartis [redacted]

3. The [redacted] Do Not Block Hikma's Entry

Novartis contends that [redacted]. Novartis granted to Hikma [redacted]. (Ex. 2 at 1.) Novartis also agreed [redacted]. *Id.* Despite these representations, Novartis now attempts to enforce the exclusionary right [redacted] to prevent Hikma from obtaining approval until after the

[redacted] when [redacted]

The [redacted] also does not justify Novartis's refusal to comply with the Settlement Agreement. [redacted] (Ex. 3.) In [redacted]" (Ex. 3, [redacted] wherein Novartis specifically agreed [redacted]. (Ex. 1, [redacted].)

4. [redacted] Does Not Give Novartis the Right to Delay Hikma's FDA Approval

Novartis has taken the extreme position that [redacted] allows Novartis to [redacted]. This reading contravenes the plain language of the section and frustrates the purpose of the agreement.

[redacted]

(Ex. 1, [redacted].) In particular, Hikma may have failed to meet the FDA's requirements and thus may not have been ready to receive final approval as of [redacted]. Alternatively, Hikma's market entry may be barred because of [redacted].

The remainder of [redacted] precludes Novartis's reading that it may frustrate Hikma's ability to fully enjoy its rights under the Settlement Agreement. For example, [redacted]. (*Id.*) And to even more clearly memorialize the parties' agreement, [redacted] includes an affirmative promise by Novartis [redacted] (*Id.* at 10-11.) Novartis cannot rely on [redacted].

5. Novartis Cannot Rely on Parol Evidence to Change the Plain Meaning of the Settlement Agreement

Because the plain language of the Settlement Agreement requires Novartis to grant Hikma [redacted], Novartis may not seek to rely on parol evidence to change the meaning of the agreement for at least two reasons.

The parties agree that [redacted]. (Ex. 1, [redacted].) Delaware contract law does not allow for consideration of parol evidence to contradict or supplement terms of an agreement if the terms are unambiguous. *Eagle Indus.*,

Inc. v. DeVilbiss Health Care, Inc., 702 A.2d 1228, 1232 (Del. 1997). A disagreement about the interpretation of the contract does not automatically create "ambiguity." *Rhone-Poulenc Basic Chems. Co. v. Am. Motorists Ins. Co.*, 616 A.2d 1192 (Del. 1992). "Rather, a contract is ambiguous only when the provisions in controversy are reasonably or fairly susceptible of different interpretations or may have two or more different meanings." *Id.*

Novartis has not identified any language in the Settlement Agreement that is ambiguous. Importantly, the parties [redacted]. Novartis should not be allowed to disrupt the clear language of the agreement through the use of misleading parol evidence.

V. CONCLUSION

For the reasons above, Hikma respectfully requests that the Court enforce the Settlement Agreement and require Novartis [redacted] or enter a judgment as to that effect.

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CERTIFICATE OF SERVICE

I hereby certify that on January 16, 2020, true and correct copies of the foregoing document was caused to be served on the following counsel of record for Plaintiff Novartis Pharmaceuticals Corporation and Novartis AG as indicated:

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